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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RIGGS II, LARRY D	
ART UNIT	PAPER NUMBER
1631	
MAIL DATE	DELIVERY MODE
12/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,099	CHEN ET AL.	
	Examiner	Art Unit	
	LARRY D. RIGGS II	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,8,9,13,14 and 62-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 8, 9, 13, 14 and 62-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/2/2010 has been entered.

Status of Claims

Claims 2, 6, 7, 10-12 and 15-61 are cancelled. Claims 1, 3-5, 8, 9, 13, 14 and 62-78 are currently pending and under consideration.

Withdrawn Rejections/Objections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn in view of the amendments filed 11/2/2010. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 8, 9, 13, 14 and 62-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (Cell, 2000, 102, 109-126) in view of Ashburner et al. (Nature Genetics, 2000, 25, 25-29) and further in view of Cho et al. (US 6,741,986).

The instant claims provide a system for identifying a drug discovery target comprising a database capable of storing genomics information, wherein

(a) the computer system is configured to (i) perform analysis of biological relationships among a database of genomics information stored as an ontology, (ii) query the database to identify disease-related pathways, and (iii) identify objects, and processes which act on the objects, wherein each of the objects or pathways is a drug discovery target;

(b) the genomics information comprises information relating to genes, their DNA sequences, their mRNA, proteins expressed from said ~enes and the biological effects of the expressed proteins, and;

(c) the ontology is organized so that: (i) each gene, mRNA, protein expressed from said gene, and biological effect is given an identifier which is related to synonyms for the identifier; (ii) each gene, mRNA, protein expressed from said gene, and biological effect is categorized by class; and (iii) the relationship of each gene, mRNA, protein expressed from said gene and disease state is defined by slots and facets.

Regarding claim 1, Hughes et al. teaches the monitoring of hundreds of cellular components with the construction of a database (compendium) of expression profiles from mutation and chemical treatment within *S. cerevisiae*, (abstract; page 124, left column, first full paragraph; figures 1-3; table 3). Hughes teaches that an expression profile allows a user to analyze the cellular transcriptional response to different steps within a pathway and enables a user to determine the affect of disease on the pathway, (page 109, right column, last

paragraph; page 118, right column). Hughes identifies components of cellular pathways as a novel targets of the drug dycyclonine, (abstract, page 115, right column; page 123, left column). Hughes shows the use of a 2-color cDNA hybridization assay to produce 300 expression profiles, (page 111, left column, last paragraph - right column, first paragraph; page 124, right column, second paragraph; Figure 1). The specification defines slots and facets as to define and structure the taxonomic relationship between classes or groups of things that share similar properties, (see specification, page 9, paragraphs 40 and 41). Hughes shows clustering analysis wherein profiles and transcripts were selected from a data matrix, and experiments and responsive genes were grouped by agglomerative hierarchical clustering, where the similarity measurement is the error-weighted correlation coefficient (page 124, third paragraph).

Hughes et al's database is not genomics information comprising relational information or where the information is stored as an ontology with identifiers or classification. Hughes et al. does not teach a computer system configured/programmed to perform the recited steps of claim 1.

Ashburner et al. teaches a gene ontology consortium of three databases to produce a structured, precisely defined, common, controlled vocabulary for describing the roles of genes and gene products in any organism, (page 26, right column, first paragraph). Ashburner et al. teaches nodes that comprise information associated with the genes, gene products and their functions and their relationships, (page 27, right column, last paragraph – page 28, left column, second paragraph). Ashburner et al. teaches unique gene ontology identifiers

and categories associated with the database components, (page 27; page 28, left column, third paragraph; Figures 1-2).

Cho et al. teaches extracting information from a plurality of sources and stored in an information store according to an ontology, (column 2, lines 28-49). Cho et al. teaches a computer system (client system) that requests information from a server computer system, which performs processing in response to the client request and provides the requested information to the client systems, (column 4, lines 3-25), which suggests that the computer system of Cho et al. can be modified to perform the recited steps of claim 1, i.e. performing analysis of relationships, querying a database and identifying objects of the database.

Regarding claims 3-5, Hughes shows the database was proprietary when produced but now is available to the public, (page 124, left column, second and third paragraphs).

Regarding claim 8, Hughes shows genes and experiments were re-ordered according to the resulting clustering similarity trees and the significance (p value) for gene regulation takes the gene measurement error and biological variation in control into account, (page 124, third paragraph; Table 3).

Regarding claim 9, Hughes shows that a compendium may be used to discover unanticipated activities of drugs and ensure that only desired treatment effects are occurring in patients, (page 124, left column, first full paragraph).

Regarding claim 13, Hughes shows expression profiles of genes of both mutant and controls of *S. cerevisiae.*

Regarding claim 14, Hughes shows multiple steps of the same pathway from the 300 expression profiles and relational database, (abstract, page 109, right column; Table 3).

Regarding claim 62, Cho et al. teaches a plurality of databases and knowledge base of scientific findings, (column 5, lines 58-66; column 7, 51-58; column 15, lines 1-14).

Regarding claim 63, Cho et al. teaches a frame-based knowledge base, (column 14, line 66 – column 15, line 3).

Regarding claim 64, Hughes teaches comparing the expression profile of a pathway to a comprehensive database of reference profiles, (page 109, right column, last paragraph).

Regarding claim 65, Hughes teaches differential gene expression profiles, (page 112; Figures 1 and 2; Table 1).

Regarding claims 66 and 71, Hughes teaches using the bootstrap method to obtain P values (significance) of each branch point in the comparison of experiment cluster tree, (page 113, left column - right column, second paragraph; Figures 1 and 2).

Regarding claim 67, Hughes teaches deviation from control experiments and profiles resulting from significant up and down regulation of genes, (page 112, right column, penultimate paragraph; Figure 2; Table 1).

Regarding claim 68, Cho et al. teaches information store is a knowledge base configured to store information according to an ontology, (column 5, lines 17-30).

Regarding claim 69, Hughes teaches an experiment cluster tree of genomic clusters that allows comparisons from experimental and control data, (page 113; Figure 1; Table 3).

Regarding claim 70, Hughes teaches a database of reference profiles used in comparison with an experimental profile, (abstract; page 109, right column, last paragraph; page 118, right column, second paragraph).

Regarding claims 72 and 73, Hughes teaches clusters resulting from both experimental and reference profiles from expression levels of microarray experiments, (pages 111 - 112; Figures 1 and 2).

Regarding claims 74 and 75, Ashburner et al. teaches information derived from a parent gene for subsets of genes and user selected genes, (page 27, right column, third paragraph; page 28, left column; figure 1).

Regarding claim 76, Hughes teaches non-overlapping clusters with a threshold of statistical significance determined by the bootstrap method yielding P values of each of the branch points in the experiment cluster tree, (page 113).

Regarding claim 77, Hughes teaches the characterization of open reading frames by comparing expression profile of deletion mutant profiles to known mutant profiles and determining a drug target based on established targets of antifungal and antimicrobial compounds, (page 113, right column, last paragraph).

Regarding claim 78, Cho et al. teaches a network of computers and a communication network, (column 4, lines 18-58).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the functional discovery process via a copendium of expression profiles of Hughes et al. with use of the ontological relations by Ashburner et al. and the computer system for information extraction and storage of a knowledge base by Cho et al. One skilled in the art would have been motivated to combine the ontological relations of Ashburner et al. with the databases of Hughes et al. because Ashburner et al. teaches that the GO ontologies produce a controlled vocabulary that can be used for dynamic maintenance and interoperability between genome databases, (page 29, right column, last paragraph). Cho et al. teaches automatically extracting information from a plurality of sources, analyzing the information and storing the information according to an ontology, (column 2, lines 28-49; column 8, line 64 – column 9, line 7) thus one of ordinary skill in the art would have been motivated to make the method of Hughes et al., Ashburner et al. and Cho et al. completely automatic by comprising a system with instructions for executing all steps of the method to take the obvious advantage of a fully automatic process, i.e. saving time and cost.

Response to Arguments

Applicant's arguments filed 11/2/2010 have been fully considered but they are not persuasive.

Regarding applicant's arguments that Meltzer does not teach ontology of the present claims, Ashburner et al. teaches the ontology of the instant claims, see above.

Regarding applicant's argument that adding data and an ontology would make Hughes' technique more complicated and not add any statistical power to his technique, Ashburner's GO ontologies only provide terms to correlate genes, gene products and their functions between databases. Hughes utilizes common terminology associated components of his compendium of expression profiles, (Figures 1-4; Table 2). Ashburner et al. also indicates that common terminology may be utilized instead of the GO identifier, (page 28, left column, third paragraph) suggesting that no data need be added to Hughes compendium.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/
Larry Riggs
Examiner, Art Unit 1631

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631